510(k) Premarket Notification
Summary of Safety and Effectiveness

MAY 0 3 2013

Submission Information

Manufacturer: Small Bone Innovations, Inc.
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Submitted By: Small Bone Innovations, Inc.
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Date: January 24, 2013, Revised March 27, 2013

Proprietary Name: SBi Anatomic Ankle Arthrodesis Interlocking Nail System

Classification name/Identification: Class II, An intramedullary fixation rod is a device intended to be implanted that consists of a rod made of alloys such as cobalt-chromium-molybdenum and stainless steel. It is inserted into the medullary (bone marrow) canal of long bones for the fixation of fractures

Product Code: HSB

Common/Usual Name and Reference Number: Intramedullary fixation rod - 21 CFR 888.3020

Substantial Equivalence: Documentation is provided which demonstrates the modified devices are substantially equivalent to the devices of the SBi Anatomic Ankle Arthrodesis Interlocking Nail System.

Device Description: The SBi Anatomic Ankle Arthrodesis Interlocking Nail System consists of implants, associated instruments, and trays. The implants are made of implantable grade titanium while the instrument components and trays are made of several materials: Aluminum, stainless steel, PEEK, POM, and composite materials.

This Premarket Notification is to add 5.0mm Tibial Locking Screws in 20 to 24mm lengths, 5.0 mm Talar Screws with Threaded Head in 40 to 44mm lengths, and 6.0mm Calcaneal Locking Screws with Threaded Head in 50 to 68mm lengths to the system.

Intended Use: The SBi Anatomic Ankle Arthrodesis Interlocking Nail System intended for tibiotalocalcaneal arthrodesis of the ankle following: Post traumatic and degenerative arthritis involving both ankle and subtalar joints, osteoarthritis, Rheumatoid arthritis, Pseudoarthrosis, Severe foot/ankle deformity, or Instability and skeletal defects after tumor resection. These include neuro-osteoarthroplasty (Charcot's foot), avascular necrosis of the talus, failed joint

replacement, failed ankle fusion, and for distal tibia fracture non-unions when used concomitantly with tibiotalocalcaneal pathology.

The implants are intended for single use only and will be offered sterile and non-sterile.

The shorter length screws being added by this Special 510(k) are made from implantable grade TiAl6V4 titanium (ASTM F136) which is the same material as the predicate screws.

The design of the shorter screws being added by this Special 510(k) are the same as the predicate screws in that the head designs of the outer and inner diameters and thread are the same. The only difference is that the modified screws are shorter in length.

Current Devices: The modified devices are equivalent to the current devices of the SBi Anatomic Ankle Arthrodesis Interlocking Nail System (K112982).

An Engineering Rationale is provided in the Bench Testing section which concludes that the bending loads will be lower if the screw is shorter while keeping the minor diameter the same.

Additionally the rationale concludes that the total mass of the new set configuration is decreasing (longer screws are being replaced by shorter screws); thus the existing sterilization parameters will still be valid.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 3, 2013

Small Bone Innovations, Incorporated
% Mr. John Minier
1380 South Pennsylvania Avenue
Morrisville, Pennsylvania 19067

Re: K130147
Trade/Device Name: SBi Anatomic Ankle Arthrodesis Interlocking Nail System
Regulation Number: 21 CFR 888.3020
Regulation Name: Intramedullary fixation rod
Regulatory Class: Class II
Product Code: HSB
Dated: April 1, 2013
Received: April 2, 2013

Dear Mr. Minier:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4 Statement of Indications for Use

510(k) Number: K130147

Device Name: SBi Anatomic Ankle Athrodesis Interlocking Nail System

Indications For Use:

The SBi Anatomic Ankle Athrodesis Interlocking Nail System is indicated for tibiotalocalcaneal arthrodesis of the ankle following:
- Post traumatic and degenerative arthritis involving both ankle and subtalar joints,
- Rheumatoid arthritis,
- Osteoarthritis,
- Pseudoarthrosis,
- Severe foot/ankle deformity, or
- Instability and skeletal defects after tumor resection.

These include neuro-osteoarthroplasty (Charcot's foot), avascular necrosis of the talus, failed joint replacement, failed ankle fusion, and for distal tibia fracture non-unions when used concomitantly with tibiotalocalcaneal pathology.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.
Division of Orthopedic Devices